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Virginia Board of Pharmacy

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Update on Laws and Regulations

The following laws, which impact the profession of pharmacy, were passed by the 2006 Virginia General Assembly and took effect July 1, 2006:

Schedule II Prescriptive Authority for Nurse Practitioners

Nurse practitioners with prescriptive authority may now prescribe Schedule II drugs, in addition to the already approved drugs in Schedules III, IV, V, and VI. As in the past, all drugs prescribed by nurse practitioners must be consistent with the agreement that provides direction and supervision between the nurse practitioner and the licensed physician. Please note that this law did not afford physician assistants this authority. Prescriptive authority for physician assistants still includes only Schedules III, IV, V, and VI. For a summary of prescriptive authority for all practitioners, refer to Guidance Document 110-8 at the following link: www.dhp.virginia.gov/pharmacy/guidelines/110-08.doc.

Restriction on Sale of Pseudoephedrine

Legislators in the General Assembly voted to enact a law restricting the sale of pseudoephedrine. This law is similar to the Executive Order that was enacted in October 2005 and expired June 30, 2006. Meanwhile the United States Congress also passed a federal law restricting the sale of pseudoephedrine-, phenylpropanolamine-, and ephedrine-based products. There are some similarities within the state and federal laws; however, pharmacists should be aware that some differences do exist. Please refer to the yellow box on the Virginia Board of Pharmacy's home page for links to copies of the state and federal laws.

Please be aware that the laws related to the sale of pseudoephedrine are not enforced by the Board of Pharmacy, and that state and local law officials, in addition to authorized Drug Enforcement Administration agents, may access the related records.

Prescription Blank Format

A 2003 law that eliminated the Virginia Voluntary Formulary delayed the effective date for changing the prescription blank format until July 1, 2006. Under the old format, blanks had two check boxes marked "Dispense As Written" or "Voluntary Formulary Permitted" that were used to either authorize or prevent substitution. §54.1-3408.03 of the Drug Control Act now requires a prescriber to indicate "brand medically necessary" on the prescription when he or she wants to prohibit substitution. If the phrase "brand medically necessary" is not indicated on the prescription blank, then the pharmacist may substitute with a therapeutically equivalent drug product, which is defined as one rated bioequivalent by the US Food and Drug Administration's "Orange Book" and can be found online at www.fda.gov/cder/ob/.

Prescribers may have already depleted their supply of the outdated prescription blank format since the law was passed in 2003, but many have not. Even though they have been specifically notified, many prescribers may still not be aware of the change in law. Pharmacists may continue to accept prescriptions in the old format, but should be aware that the old checkboxes no longer have legal meaning with respect to substitution. As of July 1, 2006, checking the phrase "Dispense As Written" will no longer prevent substitution; however, pharmacists may want to contact the prescriber to advise them if a substitution is made. For a list of frequently asked questions on this subject, click on the following link: www.dhp.state.va.us/pharmacy/pharmacy_faq.htm#PresBlank.

Periodic Regulatory Review Period

The Board is required to routinely review all regulations and began a new periodic review of its main set of regulations in February 2006. Currently, the Board is accepting public comment on any regulations that may be problematic or in need of revision. Please submit any comments in writing and identify the specific regulation(s) in question. This revision is intended to address only 18 Virginia Administrative Code (VAC) 110-20-10 et seq. The Board cannot directly address statutory requirements found in the Drug Control Act or the Pharmacy Act.

Recent Changes to Guidance Documents

Several guidance documents that interpret the Board's policy on laws and regulations were updated at the June 2006 Board meeting. Substantive changes that may affect current pharmacists and pharmacy technicians include:

- Guidance document 110-36 now indicates pharmacies performing sterile compounding should be in compliance with the physical standards of United States Pharmacopeia Chapter 797 by June 30, 2008. It originally indicated compliance by June 30, 2007. However, due to a proposed revision to the chapter and a recent change in expectation from the Joint Commission on Accreditation of Healthcare Organizations, the Board felt that this delay was appropriate.

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Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex® tablets, who recently released Zanaflex Capsules™ (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune® (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL® (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.

- When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006, for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.deadiversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

(a) Each partial filling is recorded in the same manner as a refilling,
(b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
(c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

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- Guidance document 110-26, which suggests sanctions for pharmacy inspection violations, now has revisions to numbers 1, 2, 4, and 7. The increased severity for suggested sanctions resulted from pharmacies that had relocated or remodeled without submitting an application to the Board, and were, therefore, operating in an unapproved business space with an unapproved alarm system.
- Guidance document 110-11, which references the use of STAT drug boxes in long-term care facilities, has now been revised to include assisted living facilities. However, only individuals licensed to administer drugs such as nurses, pharmacists, or prescribers may access this box and administer drugs obtained from this box. Unlicensed individuals such as medication aides may not access the STAT drug box or administer these drugs.

For a complete listing of all guidance documents, click on: www.dhp.state.va.us/pharmacy/pharmacy_guidelines.htm.

Prescription Monitoring Program Update

Reporting Prescription Data to the Program

The expansion of the Prescription Monitoring Program became effective June 1, 2006. All dispensers in Virginia (and licensed, non-resident pharmacies) are required to report information related to prescriptions dispensed in Schedules II, III, and IV twice monthly to the program. Reporting deadlines are the 10th and 25th of each month; however, data submissions may be made on a more frequent basis. The contractor responsible for data collection is Optimum Technology and may be contacted at 866/683-2476 or via e-mail at varxreport@otech.com.

One new method of reporting prescription data is via the Internet using a secure upload procedure. This is the easiest and fastest means to upload the required data. Also, the dispenser receives feedback on file acceptance or rejection in a much shorter timeframe. In most cases, entire files will not be rejected, just the individual records that do not meet criteria within a file.

Other methods for reporting include: secure file transfer protocol, diskette (includes CD, DVD, 3½ inch diskette), and a manual entry form that can be filled out online. Zero reports may also be submitted online.

Pharmacists May Now Make Requests

Pharmacists may request reports from the program on a specific patient to assist in verifying the validity of a prescription. Pharmacists may now make these requests online and receive the report in a secured Web page. This new service became available in May 2006; however, faxing and mailing of requests will still be accepted. Please note when making a request, the pharmacy must adhere to the requirements of 18 VAC 76-20-70 in the Regulations Governing the Prescription Monitoring Program relating to notification. The regulation can be found online at www.dhp.state.va.us/dhp_laws/PMP_Emergency%20regs%207-25-05.doc. Compliance with this regulation may be met by posting a sign in the pharmacy that can be easily viewed by the public, which discloses that the pharmacist may access information contained in the Prescription Monitoring Program files on Schedules II, III, and IV prescriptions dispensed to a patient.

For more information on the Prescription Monitoring Program, please click on www.dhp.state.va.us/dhp_programs/pmp/default.asp. For answers to questions, please e-mail pmp@dhp.virginia.gov or call 804/662-9129. The program fax number is 804/662-9240.

Helpful Hint: Program Web-based software for both data collection and for making requests for information works best with Internet Explorer (Version 5.5 or above).

Continuing Education Audit

Each year the Board of Pharmacy conducts a random audit of current active licensees requiring proof of successful completion of continuing education (CE) requirements for the previous two years. Pharmacists with a current active status are required to complete 15 hours of approved CE per year. Pharmacy technicians with a current active status are required to complete five hours of approved CE per year. Any CE mandated by a disciplinary procedure is in addition to the aforementioned hours.

This year was the first year that pharmacy technicians were audited. Approximately 20% of the audited pharmacy technicians could not provide proof of the required CE, or submitted certificates that did not satisfy Board requirements. A smaller percentage of pharmacists audited could not provide adequate documentation. As detailed in Guidance Document 110-04, possible disciplinary action for non-compliance with CE requirements may include a monetary penalty of $100 for each missing hour of CE, and $300 for each renewal falsely attesting to CE compliance.

Please remember that not all CE programs are approved programs. Some programs may satisfy national certification, but not state registration. Approved programs are those that are Board-approved, Accreditation Council for Pharmacy Education-approved, or Category I continuing medical education programs. For Board approval, the program provider must apply for approval at least 60 days in advance of the program being given.

The Board received a number of requests in December 2005 from licensees during the renewal period for an extension in obtaining the necessary CE credits. As mentioned in Guidance Document 110-04, the Board may grant a one-time extension. However, please be aware that if an extension is approved for a pharmacist or pharmacy technician, that person will be automatically audited the next year. Pharmacists with an approved extension must obtain 15 hours for the 2005 obligation plus 15 hours for the 2006 obligation before renewing for 2007. The original certificates for these 30 hours must be sent to the Board upon notification of the audit. Pharmacy technicians with an approved extension must obtain five hours for 2005 and five hours for 2006. The 10 original certificates must be submitted to the Board when notified of the audit. The next audit will likely be conducted in early 2007.

For more information on CE requirements, please refer to Guidance Document 110-04 found at www.dhp.state.va.us/pharmacy/guidelines/110-04%20Continuing%20education%20guide%20for%20pharmacists%2012-2005.doc.

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